REMARKS

Claims 1-27 are currently pending. Claim 1 has been amended herein. Support for the amendments can be found at least at page 6, lines 17-19. No new matter has been presented.

35 U.S.C. § 102 Rejections Overcome

Claims 1, 2, 4, 5 and 8-25 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 5,487,901 and 5,650,169 ("Conte"). Applicants disagree.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Specifically, the Examiner states that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an impermeable with an insoluble polymeric coating (*emphasis added*). (*See*, Office Action at page 3). The Examiner asserts that the method by which the tablet of claims 1, 2, 4, 5 and 8-25 is made is different from the method described in Conte but that the process by which the claimed product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of Conte. (*See*, Office Action at page 4). The Examiner also submits that the broad language of claim 1 renders the claim equivalent to the prior art because there is no upper limit for incisions and no geometric shape is required. (*See*, Office Action at page 7). Applicants traverse the rejection with respect to the claims as amended herein.

Applicants have amended claim 1, from which the remaining claims either directly or indirectly depend, to recite that film coating is impermeable to aqueous fluids and remains intact until the moment of use so that it protects the active ingredients contained therein.

Applicants submit that the process by which the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 is made imparts functional and structural limitations to the claimed product that distinguish it from the product of Conte. Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 causes structural differences between this system and the tablets taught in Conte giving the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 greater stability and a more advantageous release profile for constant steady release of the drug.

Applicants submit that while the contents of the tablets are similar, it is the differences in the process of making the tablets of claims 1, 2, 4, 5 and 8-25 that accounts for the at least 10% difference in the release profile found between the tablets of the claimed invention and those of Conte. As previously illustrated, the tablets in Conte, on average, initially release over 30% of the active ingredient and after the initial release, the release profile tends to flatten out until a subsequent release occurs. (*See*, Exhibit A, submitted on March 10, 2008). In contrast, the claimed tablet has a substantially linear drug release rate, and in general, the initial amount of the drug released is below 20%. (*See*, Exhibit B, submitted on March 10, 2008). Applicants submit that it is the incision(s) on the claimed tablet, which comprise an impermeable coating that fully covers the active ingredients and remains intact until the moment of use so that it protects the active ingredients contained therein, which alters the release profile, with a pre-determinable and programmable release rate, which differs by at least 10 % from the release profiles of Conte, *i.e.* a structural and functional limitation.

Applicants previously submitted that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system of claims 1, 2, 4, 5 and 8-25 greater stability than the tablets taught in Conte. However, the Examiner did comment on these differences in the final Office Action mailed on June 20, 2008. Further, as articulated above, Applicants have amended claim 1, from which the remaining claims depend to recite that the film coating being impermeable to aqueous fluids and remains intact until the moment of use so that it protects the active ingredients contained therein.

Applicants reiterate that the incision(s) delimited film coating of the tablet of claims 1, 2, 4, 5 and 8-25 remains intact before contact with aqueous fluids. Thus, the laser generated incisions of the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration. (*See*, Specification at page 6, lines 24-27 and Declaration under 37 C.F.R. § 1.132 of Ubaldo Conte submitted on March 10, 2008). Whereas the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient exposed. (*See*, Conte at Column 6, lines 1-4). Applicants submit that the tablet of the claimed invention is different than the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process.

Applicants submit that the process for making the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 imparts function or structural limitations to the product that distinguish

it from the product of Conte. Thus, Conte cannot anticipate claims 1, 2, 4, 5 and 8-25. Reconsideration and withdrawal is requested.

Additionally, claims 1, 3 and 6-27 remain rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US 6,599,284 ("Faour"). Applicants disagree. As stated above, in order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). The Examiner indicates that Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, an intermediate layer forming a semipermeable membrane and an inner layer or core containing active ingredient, and the dosage form comprises a passageway formed by a laser incision. (*See*, Office Action at pages 4-5). Further, the Examiner indicated that the claims did not set an upper limit of the number of incisions on the claimed tablet, and therefore, that with a large number of incisions, a passageway similar to the one disclosed in Faour, could be formed. (*See*, Office Action at pages 7-8). Applicants traverse this rejection with respect to the claims as amended herein.

Specifically, as articulated above, Applicants have amended claim 1, from which the remaining claims directly or indirectly depend, to recite that film coating is impermeable to aqueous fluids and remains intact until the moment of use so that it protects the active ingredients contained therein, which is not taught in Faour. Faour merely teaches that the passageway increases the release rate of the active agent during use. (*See*, Faour at column 4, lines 48-50). Applicants submit that Faour does not teach each and every limitation of claims 1, 3 and 6-27 and thus cannot anticipate them. Reconsideration and withdrawal is requested.

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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